UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWAR, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, AND THE DISTRICT OF VOLUMBIA, *ex rel.* MARY BIXLER WOOD,

Plaintiffs,

v.

SIEMENS MEDICAL SOLUTIONS USA, INC., SIEMENS HEALTHCARE DIAGNOSTICS, INC., AND SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS GMBH,

Defendants.

MEMORANDUM & ORDER
21-CV-1947 (MKB)

MARGO K. BRODIE, United States District Judge:

Plaintiff-Relator Mary Bixler Wood ("Relator"), acting on behalf of the United States of America, thirty states, and the District of Columbia, commenced the above-captioned action against Defendants Siemens Medical Solutions USA, Inc., Siemens Healthcare Diagnostics, Inc., and Siemens Healthcare Diagnostics Products GmbH (collectively, "Siemens" or "Defendants") on April 12, 2021.[1] (Compl., Docket Entry No. 1.) On March 29, 2022, Relator filed an

[1] By stipulation dated June 15, 2021, Relator and the United States agreed to allow the United States until December 10, 2021 to determine whether to intervene in this action. (Stip. & Order, Docket Entry No. 3.) The United States subsequently declined to intervene, and the Court

Amended Complaint alleging that Defendants violated provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA") barring the presentation of false claims, the use of false statements, and conspiracies to violate the FCA as well as various state law FCA analogs.[2] (Am. Compl., Docket Entry No. 8.)

Defendants move to dismiss the Amended Complaint pursuant to Rules 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, and Relator opposes the motion.[3] For the reasons set

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ordered the Complaint to be unsealed and served upon Defendants. (Order dated Dec. 14, 2021, Docket Entry No. 4.)

[2] Relator claims that Defendants violated the California False Claims Act, Cal. Govt. Code § 1265 *et seq.*; the Colorado Medicaid False Claims Act, Col. Rev. Stat. § 25.5-4-303.5 *et seq.*; the Connecticut False Claims Act for Medical Assistance Programs, Conn. Gen. Stat. § 17b-301 *et seq.*; the Delaware False Claims and Reporting Act, Del. Code. Ann. tit. 6, § 1201 *et seq.*; the District of Columbia False Claims Act, D.C. Code Ann. § 2-308.03 *et seq.*; the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat § 175/1 *et seq.*; the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq.*; the Iowa False Claims Act, Iowa Code § 685 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*; the Massachusetts False Claims Law, Mass. Gen. Law. ch. 12, § 5A *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. § 357.010 *et seq.*; the New Hampshire False Claims Act, N.H. Rev. Stat. § 167:61-a *et seq.*; the New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*; the New Mexico Medicaid False Claims Act and Fraud Against Tax Payers Act, N.M. Stat. Ann. § 27-14-1 *et seq.* and § 44-9-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, 63 Okla. St. Ann. § 5053 *et seq.*; the State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. § 71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002 *et seq.*; the Vermont False Claims Act, 32 V.S.A. § 630 *et seq.*; the Virginia Fraud Against Taxpayers Act., Va. Code Ann. § 8.01-216.1 *et seq.*; and the Washington State Medicaid Fraud False Claims Act, Rev. Code Wash. § 74.66.0005 *et seq.*

[3] (Defs.' Mot. to Dismiss ("Defs.' Mot."), Docket Entry No. 25; Defs.' Mem. in Supp. of Defs.' Mot. ("Defs.' Mem."), Docket Entry No. 26; Pl.'s Mem. in Opp'n to Defs.' Mot. ("Pl.'s Opp'n"), Docket Entry No. 29; Defs.' Reply Mem. in Supp. of Defs.' Mot. ("Defs.' Reply"), Docket Entry No. 28.)

forth below, the Court grants Defendants' motion and dismisses the Amended Complaint. The Court grants Relator leave to file a second amended complaint within thirty days of this Memorandum and Order.

I. Background

The Court assumes the truth of the factual allegations in the Amended Complaint for the purposes of this Memorandum and Order.

a. The parties

From May of 2014 to December of 2015, Relator served as "Director of Compliance for a Siemens contractor that performed special projects for Siemens, including a project designed to qualify the shipping containers used by Siemens to maintain the temperature requirements during transport of the medical devices." (Am. Compl. ¶ 10.) Between February 17, 2016 and April 29, 2016, "Relator served as a contract employee directly for Siemens as a Project Manager for implementation and management of cold chain transportation processes." (*Id.*)

Siemens Medical Solutions USA, Inc., which is the parent company of Siemens Healthcare Diagnostics, Inc., is a Delaware corporation conducting business in Malvern, Pennsylvania and operating a distribution center in Plainfield, Indiana "where all domestic Siemens IVD shipments originate." (*Id.* ¶ 11.) Siemens Healthcare Diagnostics, Inc., a wholly-owned subsidiary of Siemens Medical Solutions USA, Inc., is a California corporation conducting business in Tarrytown, New York which "is responsible for maintaining premarket approvals and 510(k) clearances for . . . medical devices . . . as well as for maintaining compliance with applicable regulatory controls, such as FDA's Quality System Regulations, relating to those devices." (*Id.* ¶ 12.) Siemens Healthcare Diagnostics Products GmbH, a corporate affiliate of Siemens Healthcare Diagnostics, Inc., is a German corporation principally

operating in Marburg, Germany which "has oversight of quality issues at other corporate affiliates, including quality issues relating to the shipping and storage of devices from the ADC in Plainfield, Indiana." (*Id.* ¶ 13.)

b. In vitro diagnostic medical devices

In vitro diagnostic ("IVD") medical devices "are tests (frequently referred to as assays) which are performed on blood, saliva or tissue samples that can be used to monitor a person's overall health to help cure, treat or prevent disease as well as to identify patients who are likely to benefit from specific treatments or therapies." (*Id.* ¶ 2 (citations omitted).) "An IVD that cannot be relied upon to provide an accurate measurement pertaining to the very medical issue for which the test has been designed is, by definition, a materially defective product for which neither payment nor reimbursement may be required under law or contract." (*Id.* ¶ 3.) "Many . . . IVD medical devices are temperature-sensitive and, in many cases, must be maintained in a refrigerated or frozen condition until they are used." (*Id.* ¶ 4.) "An IVD's value in accurately measuring and detecting analytes or markers in the human body . . . cannot be maintained if the temperature conditions necessary to meet the IVD's design and performance specifications do not exist." (*Id.* ¶ 7.) The failure of IVDs "presents a serious public health risk" because "[f]aulty diagnostic tests could result in false-positives or false-negatives, thus causing misdiagnosis" which could "lead to deferred treatments, unnecessary treatments, death, and serious injuries, among other negative consequences." (*Id.* ¶ 101.)

c. Defendants' IVD business

"Siemens is among the largest IVD manufacturers in the world," and in 2015 "was the largest IVD manufacturer globally and the second leading IVD company, in terms of market share, in the United States." (*Id.* ¶ 77.) "Siemens IVDs are reimbursed by Federal Health Care

Programs." (*Id.* ¶ 82.) "Siemens affirmatively contracts with a third party to provide government reimbursement information for its entire menu of IVDs through an online product called CodeMap." (*Id.*) "IVDs . . . are reimbursed by Federal Health Care programs on the assumption that the IVDs are reliable, safe and effective for medically necessary diagnosis and treatment." (*Id.* ¶ 84.) Siemens sells IVDs to the Department of Defense and the Department of Veteran Affairs. (*Id.* ¶ 85.) In addition, Siemens has had contracts for IVD products with the Department of Health and Human Services, the Department of the Air Force, the Federal Bureau of Prisons, and the Department of Navy. (*Id.* ¶ 88.) "Individual States also purchase Siemens IVDs for use by State laboratories and health systems." (*Id.* ¶ 90.)

"Many Siemens IVDs . . . are highly temperature-sensitive devices that must be maintained in a refrigerated or frozen condition in order to ensure reliability, safety and efficacy in clinical use." (*Id.* ¶ 96.) In internal memoranda, "Siemens has recognized that IVDs are sensitive to temperature changes and must [be] stored and shipped under specific controlled temperature conditions . . . to ensure product integrity is maintained throughout the distribution process." (*Id.* ¶ 98 (internal quotation marks omitted).) Siemens conducts stress testing, exposing its devices to different temperatures "for particular defined intervals," "[t]o assess whether its devices may be exposed, even briefly, to various temperature ranges." (*Id.* ¶ 97.)

d. Allegations of misconduct

Relator contends that "[f]or many years, Siemens has knowingly shipped temperature-sensitive IVDs well outside their FDA-approved or -cleared temperature ranges." (*Id.* ¶ 104.) Siemens IVDs, which are stored at and shipped from Plainfield, Indiana, (*id.* ¶ 108), "were cleared or approved by [the] FDA for specific temperature ranges," (*id.* ¶ 109). "The labels on Siemens IVDs include temperature storage requirements and representations about shelf life"

which "are based on purported testing conducted under the temperature conditions cleared or approved by the FDA." (*Id.* ¶ 107.) "Upon information and belief, Siemens has not conducted stability testing to validate the accuracy of the information on its device labels." (*Id.*) "Siemens knows that the expiration and shelf life information on its devices is inaccurate" and has conducted stability testing which "demonstrated that certain devices either fail or are not safe and effective within the shelf life stated on the device labels." (*Id.*)

Siemens uses corrugated boxes lined with foam called "shippers" to ship IVDs. (*Id.* ¶ 111.) After orders are placed, Siemens IVDs are "placed in the shipper, labeled, packaged, and given to a carrier (such as FedEx, UPS, etc.) for distribution." (*Id.* ¶ 110.) During the shipping process, IVDs "are not kept within temperature-controlled storage conditions" and "are removed from temperature-controlled storage conditions up to hours at a time in order to be packaged for shipment." (*Id.*) Siemens is aware from its field tests that its "shipped IVD devices reach temperatures well outside their approved or cleared temperature ranges." (*Id.* ¶ 113.) Between 2009 and 2015, companies hired by Siemens demonstrated that shippers used by Siemens "failed to maintain devices within required temperature ranges." (*Id.* ¶ 114.) Tests conducted in 2009, 2010, 2012, and 2014 showed that shippers failed to maintain internal temperatures between two and eight degrees Celsius over a standard shipping time. (*Id.* ¶¶ 117–18.) "Siemens was aware since at least 2009 that the shippers used by the company to transport IVDs to customers resulted in exposure of IVDs to temperatures well outside of their FDA-approved frozen or refrigerated ranges, rendering the shipped devices both adulterated and misbranded, with no assurances or reliability, safety or efficacy." (*Id.* ¶ 133.) "Siemens is fully cognizant of the safety risks that non-compliant temperature conditions create for its IVD products generally." (*Id.* ¶ 147.)

Relator also contends that Siemens caused others to submit false claims, which "did not

disclose . . . the compromised reliability, safety and efficacy of the IVDs resulting from Siemens' non-compliance with FDA medical device laws and regulations," to Federal Health Care Programs for the use of its compromised IVD products. (*Id.* ¶ 171.) "Siemens also sold those compromised IVD products directly to the Government." (*Id.* ¶ 172.)

II. Discussion

a. Standard of review

In reviewing a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a court "must construe [the complaint] liberally, accepting all factual allegations therein as true and drawing all reasonable inferences in the plaintiffs' favor." *Sacerdote v. N.Y. Univ.*, 9 F.4th 95, 106–07 (2d Cir. 2021) (citing *Palin v. N.Y. Times Co.*, 940 F.3d 804, 809 (2d Cir. 2019)); *see also Vaughn v. Phoenix House N.Y. Inc.*, 957 F.3d 141, 145 (2d Cir. 2020) (same). A complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Bacon v. Phelps*, 961 F.3d 533, 540 (2d Cir. 2020) (quoting *Twombly*, 550 U.S. at 570). A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Matson v. Bd. of Educ.*, 631 F.3d 57, 63 (2d Cir. 2011) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *Cavello Bay Reinsurance Ltd. v. Shubin Stein*, 986 F.3d 161, 165 (2d Cir. 2021) (quoting *Iqbal*, 556 U.S. at 678). Although all allegations contained in the complaint are assumed to be true, this tenet is "inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678; *Vaughn*, 957 F.3d at 145 (quoting *Iqbal*, 556 U.S. at 678).

b. Relator's FCA claims

Defendants argue that the Amended Complaint should be dismissed because Relator has failed to allege a false claim. (Defs.' Mem. 1.) In support, Defendants argue first, that Relator

has not alleged a facially plausible claim and contends that "[t]he utter implausibility" of the "far-reaching scheme" is "outlandish" and requires dismissal. (*Id.* at 25, 27.) Defendants point to the absence of evidence documenting customer complaints and product failures stemming from extreme product temperatures. (*Id.* at 27.) Second, Defendants argue that "Relator has failed to meet Rule 9(b)'s [particularity] requirement," (*id.* at 25), as "she has not pleaded with particularity any facts showing that any of [Defendants'] IVDs were ever damaged due to shipping conditions and then used to report results on patient samples . . . , and she has not pleaded with particularity any facts showing that any of [Defendants'] customers submitted 'actual false claims' to the government," (*id.* at 28). They contend that Relator's failure to allege failures in IVD test results stemming from Defendants' shipping practices is dispositive. (*Id.* at 15.) Third, Defendants assert that "Relator has failed to plead falsity." (*Id.* at 25.) Fourth, Defendants argue that Relator failed to plead materiality. (*Id.* at 38.) Defendants argue that the government's "continu[ed] payment[s] and lack of any action . . . following Relator's multiple [c]omplaints demonstrates that any issues raised by Relator are not a material consideration for its continuing purchases and reimbursement." (*Id.*) Defendants also argue that Relator's conspiracy claims should be dismissed because "Relator has failed to plead an underlying FCA violation" and only alleges a conspiracy among employees and wholly-owned subsidiaries of the same corporation. (*Id.* at 39–40.)

Relator alleges that she has satisfied Rule 9(b)'s particularity requirement by "describing in meticulous detail how Siemens engaged in the knowing shipment of adulterated and misbranded IVDs in violation of FDA quality and marketing regulations." (Pl.'s Opp'n 26.) Relator notes that she alleges that "(1) [Defendants'] shippers were incapable of maintaining required frozen and refrigerated temperature parameters for its IVDs; (2) these thermal failures

occurred within [Defendants'] average shipping times so that the actual shipment of adulterated and misbranded IVDs was assured;" and (3) Defendants were "well aware of these facts" and chose to continue shipping "IVDs in deficient shipping containers, thereby knowingly exposing numerous IVDs to dangerous temperature excursions and rendering them adulterated and []misbranded under the FCA." (*Id.* at 25.) Relator states that she "is not required . . . to identify specific IVD shipments exposed to non-compliant temperature excursions" prior to discovery because "she has otherwise alleged highly detailed and compelling facts establishing a general business practice which ensured that numerous IVDs were so exposed and that Siemens knew this to be true." (*Id.* at 26.) Relator also contends that she did allege that Defendants violated FDA regulations and submitted false claims. Specifically, she "allege[d] in extraordinary detail [Defendants'] knowing failure to ship IVDs . . . in a temperature-compliant fashion," (*id.* at 5), and also "alleged specific facts concerning numerous Government contracts and purchases of Siemens IVDs . . . during the same period when [she] alleges that Siemens IVDs were adulterated and misbranded for failure to comply with FDA quality and marketing regulations governing temperature requirements," (*id.* at 6). In addition, Relator argues that her claims are plausible and adequately allege materiality. She contends that Defendants' "assumption that government regulators and other third parties necessarily would have uncovered the misconduct being alleged had it occurred is simply unfounded," (*id.* at 12), and argues that she satisfies the materiality requirement by alleging that Defendants' failure to disclose its violations of FDA regulations "breached essential requirements of Government contracts mandating FDA compliance and rendered those IVDs non-reimbursable under Federal Health Care Programs," (*id.* at 33). Relator also argues that she adequately pleaded a conspiracy claim and that the intra-

corporate doctrine is inapplicable because she has alleged conduct constituting a criminal conspiracy. (*Id.* at 39.)

The FCA "provides that a person may bring a civil action for violating the FCA on behalf of that person and the United States Government." *United States ex rel. Yu v. Grifols USA, LLC*, No. 22-CV-107, 2022 WL 7785044, at *1 n.1 (2d Cir. Oct. 14, 2022) (citing 31 U.S.C. § 3730(b)(1)). The FCA imposes liability for, among other things, "knowingly" presenting or causing to be presented a false or fraudulent claim "for payment or approval." 31 U.S.C. § 3729(a); *Doe 1 v. EviCore Healthcare MSI, LLC*, No. 22-CV-530, 2023 WL 2249577, at *2 (2d Cir. Feb. 28, 2023) ("The FCA imposes liability on 'any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.'" (quoting 31 U.S.C. § 3729(a)(1)(A))); *Lee v. N. Metro. Found. for Healthcare, Inc.*, No. 21-CV-2155, 2022 WL 17366627, at *1 (2d Cir. Dec. 2, 2022) (same). "FCA liability can be premised on 'specific representations about the goods or services provided' which, while not expressly false, 'fail[] to disclose noncompliance with material statutory, regulatory, or contractual requirements.'" *Pfizer, Inc. v. United States Dept. of Health & Human Servs.*, 42 F.4th 67, 78–79 (2d Cir. 2022) (quoting *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016)). Although Congress has repeatedly amended the FCA, "its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Escobar*, 579 U.S. at 182; *see also United States, ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419 (2023) ("The Act . . . impose[s] civil liability for many deceptive practices meant to appropriate government assets."); *United States v. Wells Fargo & Co.*, 943 F.3d 588, 596 ("[T]he objective of Congress was broadly to protect the funds and property of the Government from fraudulent claims, regardless of the particular form, or function, of the government instrumentality upon

which such claims were made." (quoting *Rainwater v. United States*, 356 U.S. 590, 592 (1958))). A "claim" includes direct requests to the government for payment as well as claims for reimbursement under federal benefits programs. *Escobar*, 579 U.S. at 182. "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 109 (2d Cir. 2021) (quoting *Escobar*, 579 U.S. at 181).

"Qui tam complaints filed under the FCA, because they are claims of fraud, are subject to Rule 9(b)." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Resp., Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (citing *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016)). "Rule 9(b) requires that '[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.'" *Ladas*, 824 F.3d at 25 (alteration in original) (quoting Fed. R. Civ. P. 9(b)); *Grifols*, 2022 WL 7785044, at *2 (same). "Under Rule 9(b), the party alleging fraud must: '(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.'" *Doe 1*, 2023 WL 2249577, at *2 (quoting *Chorches*, 865 F.3d at 81). In other words, Rule 9(b) "requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *HDtracks.com, LLC v. 7digital Grp. PLC*, No. 18-CV-5823, 2019 WL 6170838, at *10 (S.D.N.Y. Nov. 19, 2019) (quoting *Minnie Rose LLC v. Yu*, 169 F. Supp. 3d 504, 511 (S.D.N.Y. 2016)). As the Second Circuit has explained, "[t]he purpose of Rule 9(b) is threefold — it is designed to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *Wood ex rel. U.S.*

v. Applied Rsch. Assocs., Inc., 328 F. App'x 744, 747 (2d Cir. 2009) (quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)). "'Bare-bones allegations' therefore do not suffice." *McNaughton v. Young Living Essential Oils, LC*, 67 F.4th 89, 99 (2d Cir. 2023) (quoting *Lundy v. Cath. Health Sys. of Long Island Inc.*, 711 F.3d 106, 119 (2d Cir. 2013)).

"[T]o survive dismissal under Rule 9(b) when the complaint pleads only on information and belief that fraudulent claims were actually submitted to the United States, a plaintiff must (1) 'make plausible allegations that the bills or invoices actually submitted to the government were uniquely within [the defendant's] knowledge and control,' and (2) 'adduce specific facts supporting a strong inference of fraud.'" *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 248 (2d Cir. 2019) (quoting *Chorches*, 865 F.3d at 83 (internal quotation marks omitted)); *see also United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020) ("'Rule 9(b) permits knowledge to be averred generally,' but plaintiffs . . . still must 'plead the factual basis which gives rise to a strong inference of fraudulent intent.'" (quoting *O'Brien*, 936 F.2d at 676)); *Chorches*, 865 F.3d at 86 ("[A] complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge.").

Relator has failed to satisfy Rule 9(b)'s particularity requirement. Relator claims that Defendants "knowingly shipped temperature-sensitive IVDs well outside their FDA-approved or -cleared temperature ranges." (Am. Compl. ¶ 104.) According to Relator, the FDA only "cleared or approved" the IVDs "for specific temperature ranges," (*id.* ¶ 108), meaning that Defendants' shipping practices "rendered the shipped devices both adulterated and misbranded, with no assurances of reliability, safety or efficacy," (*id.* ¶ 133). Relator alleges that Defendants'

shipping practices caused others to submit false claims to the federal and state governments which "did not disclose . . . the compromised reliability, safety and efficacy of the IVDs" stemming from their "non-compliance with FDA medical device laws and regulations." (*Id.* ¶ 171.) However, Relator does not allege that Defendants' shipping practices compromised any IVDs for which claims to governments were actually submitted by Defendants. *See Conte v. Kingston NH Operations LLC*, 585 F. Supp. 3d 218, 239 (N.D.N.Y. 2022) (finding that the plaintiff failed to satisfy Rule 9(b) because she did "not allege[] facts plausibly suggesting how a particular submitted claim is false or fraudulent"). Instead, Relator presumes that Defendants' shipping policies resulted in IVD testing failures, but does not present allegations that the testing failures occurred. Relator's failure to do so is fatal to her FCA claims. *See Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 302 (S.D.N.Y. 2013) (finding that plaintiff failed to satisfy Rule 9(b) because he did not "identify a particular false claim that was submitted to the government for payment by any [d]efendant"); *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 268 (W.D.N.Y. 2010) (finding Rule 9(b) unsatisfied where plaintiffs did not "identif[y] any particular case where a fraudulent bill was presented"). Accordingly, the Court dismisses Relator's FCA claims.

c. Relator's state law claims

As a result of the Court's dismissal of Relator's FCA claims, the Court declines to exercise supplemental jurisdiction over Relator's state law claims. *Fernandez v. Zoni Language Ctrs., Inc.*, 858 F.3d 45, 46 n.1 (2d Cir. 2017) (affirming district court's decision declining to exercise supplemental jurisdiction over state law claims after dismissing plaintiffs' federal claims); *All. of Auto. Mfrs., Inc. v. Currey*, 610 F. App'x 10, 14 (2d Cir. 2015) (holding it was "not improper for the court to decline to exercise its supplemental jurisdiction" after it properly

dismissed the plaintiff's federal claims); *One Commc'ns Corp. v. J.P. Morgan SBIC LLC*, 381 F. App'x 75, 82 (2d Cir. 2010) ("If all of a plaintiff's federal claims are dismissed, a district court is well within its discretion to decline to assert supplemental jurisdiction over any state law claims[.]" (citing *WWBITV, Inc. v. Vill. of Rouses Point*, 589 F.3d 46, 52 (2d Cir. 2009))). Accordingly, the Court dismisses without prejudice Plaintiff's state law claims.

III. Conclusion

For the reasons stated above, the Court grants Defendants' motion and dismisses Relator's claims without prejudice. The Court grants Relator leave to file a second amended complaint. Any second amended complaint must be filed within thirty days from the filing of this Memorandum and Order. If a second amended complaint is not timely filed, the Court will direct the Clerk of Court to enter judgment and close this case.

Dated: September 14, 2023
Brooklyn, New York

SO ORDERED:

s/ MKB
MARGO K. BRODIE
United States District Judge